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Biopure Presentation by Thomas Moore, CEO

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Jeff Meecham:

Good afternoon. My name is Jeff Meecham, I'm one of Biotech's research team here at UBS. It's my pleasure to introduce Thomas Moore, CEO of Biopure Corporation.

Thomas Moore:

Thank you very much. Good afternoon everybody. Thank you for joining us today. We'll start off with the always popular disclaimer side, which none of you have ever seen before. I will point out thought that this one is slightly different from the other ones because it does say that the content of this presentation does not necessarily reflect the position or the policy of the government or department of defense. We have to say that because so much of our trauma research is being overwritten by the US Military. I'm told that Colin Powell is also obligated to put this disclaimer in front of any speech he makes. So, like I said, on to talking about BioPure and in particular our product Hemopure, which is a first in class oxygen therapeutic in a whole new class of pharmaceuticals designed to be intravenously administered to deliver oxygen to tissues. We initially developed this product to provide an oxygen bridge to the treatment of the immediate signs and symptoms of acute surgical anemia, but we have been working very hard over the last few years to also develop initial indications including use in trauma, ischemia, particularly associated with surgery and in use with cancer. And I'll talk about more of that as we go forward.

How do we make our product? Our product is a biologic by the definition, that is it is a highly refined form of hemoglobin drawn from an animal source, specifically from the red blood cells of cows, certainly a plentiful source. We have special herds in central Michigan that are sequestered from other animals and whose feeding and other care is carefully monitored by folks contracted by the company. Periodically, through these cows are invited to take a trip to Pennsylvania. There, somewhat reluctantly they give up 50 - 22 liters of their blood, prior to being slaughtered for meat. That blood is held until the cows are cleared for human consumption and then the blood is sent across town to our initial processing facility where the red blood cells are taken out of the plasma and then broke open and the hemoglobin extracted. That is the biologic product that's the core of our products. That product is then purified through several

steps, including a proprietary high performance liquid chromatography step, so it really gets down to just the pure hemoglobin itself, in it's so-called native hemoglobin form. We then stabilize that hemoglobin and use a polymerization process to create an elected size for this hemoglobin which is ideal for its primary job for transporting oxygen through the blood stream and for doing so as safely as possible. The resulting product offers several advantages compared to human red blood cells.

First of all, because it's pure hemoglobin with no other allergenic material, it's compatible with all blood types. In fact, it's compatible with all species that use hemoglobin to carry oxygen around their systems. Our veterinarians who use our veterinary product has transfused this product into over 37 species, from alligators, to birds. It's worked with all of them. Second, it's a highly stable product. In fact, the shelf life of this product is three years. And that three years stability is importantly at room temperature, which we define as up to 80 degrees Fahrenheit. Unlike human blood, which once it is extracted from the body, has a life time of only 42 days and only then if it is kept refrigerated through that period of time. And because we are a carefully manufactured pharmaceutical quality product, we offer consistency potency, purity and stability, something which can't be guaranteed with a product derived from directly from a human source of red blood cells, particularly because the potency of red blood cells decline sharply after the initial donation occurs. In fact, after roughly 8 days, the capacity of red blood cells to carry oxygen around the system immediately upon transfusion declines by over 50%. In fact, it takes several hours before human red blood cells that are transfused to fully regain their oxygen carrying capacity. So, we deliver oxygen immediately upon transfusion which red blood cells cannot. And of course, finally, we have an abundant and a well controlled raw material source, something which can't be said for the human population. So, that's the nature of our product and it is a breakthrough characteristics in terms of how it's been compared to red blood cells, but its breakthrough in other ways as well, and that is in the way it actually works within the human body.

Here you see a representation of a situation where the patient which initially has normal concentration of red blood cells and as you can see, the red blood cells are carrying oxygen, those little bubbles that come off through both major arteries and then the finer capillaries that branch off to the side. In the center of these three graphic representations, you see the situation where that patient becomes anemic due to sudden blood loss from surgery or from trauma or some other source. And a couple of things happen. First of all the fewer red blood cells distribute less oxygen which you can see here, but secondly the body closes off the smaller arteries and capillaries to conserve these red blood cells for the major organs of the body, ultimately the brain and the heart and does not let these red blood cells distribute oxygen through the rest of the body. In the

third picture you can see what happens when Hemopure is added to the system. First of all, the total distribution of oxygen goes way up. In part, that's because our product is three to four times more efficient than human red blood cells in actually delivering oxygen to the body. Human red blood cells give out only a third to a half of the oxygen they have per pass through the body, while our product gives off all of the oxygen it carries. The second important difference you can see in this as well though, is our product, because it is particle size, is one one-thousandth the size of a red blood cell, can bypass the restrictions that the body has put in place when it feels it's short of red blood cells. In this case, you can see our product is going down that constricted artery on the right and distributing oxygen to tissues which otherwise would get no oxygen whatsoever. This capacity and capability is important for the other indications we have under development such as use in surgical ischemia to bypass the short term ischemia which sometimes results from cardiac surgery, once the clots are being broken up, and also in cancer where we can oxygenate any anoxic cancer tissue which otherwise would be extremely resistant to radiation or chemotherapy and make that tissue 30-50 times more responsive to both radiation and chemotherapy. So, that's our technology and our product, and some of what it can do.

Now, not so reluctantly, I'd like to talk about our company. Our company BioPure is the leading developer of oxygen therapeutics. We define leading as, we are the only company that has had actually two different products in this category actually approved by regulatory authorities. We believe we are faced with a multi billion dollar market opportunity based on a growing global need for a blood substitute, but also these additional applications would stem from the unique physical structure of the product that we created, and third, as a company we are really poised for commercialization. We own all the rights to our patented products and technology with very strong and long-lasting patent rights. And we have the largest validated manufacturing capacity to produce these products. Finally, we have made significant changes in our senior management in order to lead us on the transition of being a fully commercialized firm. Let me talk about that just briefly.

Over the past year, we have made several changes designed to strengthen the company in three key areas. Marketing, manufacturing, and finance. In the marketing area, the first thing the board did was bring me on board. I've been working in the pharmaceutical industry for over 15 years. Initially with a small product company called Procter & Gamble where I ran the worldwide pharmaceuticals and the over-the-counter drug business for 4 years including roughly $850,000,000 of prescription drug business. I then spent 7 years running Nelson Communications, one of the leading sales and marketing services providers for the pharmaceutical industry, participating in dozens of product launches and working with over 200 prescription drug company clients.

And so, I come in to really help with the transition of this company building a boat by general management as well as pharmaceutical marketing experience. Beyond that, we have added individuals like Donald Wolf on the bottom there, who is a very experienced medical education person to improve the quality of our scientific exchange. On the manufacturing side, we reassigned individuals from within the company Karl Rausch and Rick White to focus on a area we call process technology, designed to improve the reliability, stability and the expandability of our national manufacturing process both to increase the capacity of our Cambridge facility to its maximum amount, but also to pave the way for the construction for our new planned facilities. And finally, we added Ron Richards who has extensive investment banking experience with VanCasper and Security Pacific to come in as CFO to improve our ability to work with the street and to lay the groundwork for the financing work we need to do in the years ahead upon the expansion of the company.

Our board of directors is listed on the right. It's a very distinguished one. Lead by Dr. Charles Sanders who is previously chairman and CEO of Glaxo as well as President of Massachusetts General Hospital, Jim Jellison who is part co-founder of the company as well as co-founder of Gulf and Western. Karl Rausch, who is also co-founder of the company, C. Everett Coop who of course is C. Everett Coop, but he's also been working with blood substitutes for a number of years.

More details then about our products. We have two products, hemopure, the human version and Oxyglobin the veterinary version. Hemopure has been approved for the treatment of acute surgical anemia in South Africa since 2001. We applied for approval in the US in 2002, the US FDA responded to us in the end of July this year, and we are in the process of recurring answers to the many questions they asked of us, and I'm going to give you more details on that in just a minute. Our veterinarian product was approved for use in the US in 1998 and in Europe in 1999, and more importantly, both our products have earned something called the EDQM Certificate of Suitability. This is a certificate issued by the EMEA, the European Medicine Agency and it's a requirement for the distribution and sale of any product in Europe based on bovine products, based on any kind of biological material related to cows based on the well-known European concern about BSE. This certificate certifies that we demonstrate to their satisfaction that our manufacturing process can eliminate the viral and whatever you chose to call the [prions ?] associated with BSE, as well as six other key pathogens that can be transmitted through cows, and that's the fundamental basis for the overall safety pitch of the product from the standpoint of viral infection. On our veterinary size business we sold over 137,000 units so far and as I mentioned before, our veterinarians have been very aggressive in

using that on dogs, yes, but on a wide variety of other species as well and quite successfully.

As I mentioned earlier, we submitted our BLA in July 2002. The FDA got back to us at the end of July 2003, somewhat ahead of the regulatory schedule that had been set up which would have ordinarily been required a response by the end of August. The letter they sent us indicated the following: First, that they had completed their review of our application and second, that they are not going to ask us anymore questions, these are all the questions they have to ask. And that's a good thing for us too, because they asked a lot of questions. With about 50 representing substantial BioPure effort in order to fully respond. Since then in our dialogue with the agency, the agency has referred to these questions repeatedly as our roadmap and that's a roadmap we intend to follow. After careful review of the letter, we knew that we needed to ask the agency some questions to both clarify what they meant in their questions, but also to find mutually agreed upon ways to narrow the scope of the data they'd been asking for in order to get the answers back to them as expeditiously as possible. We announced in August we would seek a meeting with FD in September to get some of these questions answered. Since then, the agency has been extraordinarily responsive to our questions. In fact, of the six major interactions we had with the agency about this letter, they have come back to us with responses to the questions and issues we raised in general in less than a day. In some cases less than an hour. And as such, we've been in a happy position of seeing most of our questions getting answered without the need for a meeting and by now, most of them, in fact, have been resolved with one or two still outstanding. So, as we get this guidance back, we are simultaneously developing our own internal time line for when we are going to complete our response back to the FDA. We promised our investors that we would try to get all of our answers back from FDA in September and then come back to them with a specific information about the time line for a response, and we are right on track to do that. We expect to be able to do so in the month of October. In the meantime, we are busy answering questions, and in fact, preparing our response. We'll simply be able to provide a better guidance as to when that response will be completed by the end of October. In large part, that'll be dependant on how much effort and time is required. For some of the questions which the agency asked which require us to go back to our investigator sites and get more raw information from them. In some cases about our product, and in other cases about historical data on issues like transfusions and like of those sites. So, that's where we stand there.

What's this about market opportunity? Well we show here a quick summary of the opportunity we see for this product based on the US market alone. And I'll run through it for you very quickly. Our initial marketing strategy of

filing for approval of this product for use in orthopedic surgery is to go after the part of the orthopedic surgery market that is most receptive to the opportunity to use an alternative to [alogenic ?] blood and that is the population that has already decided they want to participate in bloodless or blood avoidance surgery programs. Within the US in orthopedic surgery alone, that represents a potential market of $300,000,000 for us which assuming only 30% market penetration is roughly a $90,000,000 revenue opportunity short-term. Assuming we can expand that to use on all other bloodless surgery that would increase the - more than double the total size of that total market opportunity from our standpoint. Again, assuming relatively conservative penetration of that market. Longer term as we can expand our generation to general surgery, that would open up a huge market of $700,000,000 to us in addition to those earlier smaller markets. Our second key priority is to use this product in trauma. In ambulances and in the military applications where blood would not otherwise be available. Here in the US alone, we see the total market of about $250,000,000. The opportunity for us at about $130,000,000. We expect to begin the clinical trials leading to establish that indication in the next 3-6 months.

The next opportunity is in surgical ischemia. That is the use of this product can [combinative ?] with procedures such as stint placement and angioplasty where it's already been well established that 20-30% of patients can suffer from side effects associated with this surgery related to other ischemic events which occur as a result of that surgery. Namely, when a clot gets displaced, the fragments of that clot can lodge further down the blood stream, in the heart or the brain, creating other short term and sometimes long term side effects. Assuming only 50% of penetration of that market in the US alone, that would represent about a $350,000,000 opportunity. Again, assuming the cost to unify our product at around $700. And finally in cancer therapies as I have already indicated. We see a huge opportunity in improving the quality of treatment for solid tumors like [leopastoma ?] the brain, non-small cell lung cancer, pancreatic cancer, and the like - where solid tumors are created that are so aggressive that the interior actually becomes anoxic, that is that tissue more-or-less goes to sleep from lack of oxygen, but therefore, becomes incredibly resistant to treatment by radiation or chemotherapy. We believe we can undo that with the application of our product. So, that's the opportunities we see it today.

Is there potential even beyond that? We think there is. One key area is based on the potential large scale shortages in the supply of blood itself. Quite simply, the relationship of blood supply and demand is changing rapidly and its changing in the direction of creating broad scale shortages in this critical area. The reasons are simple. In order to insure the safety of the blood supply, we are increasingly restricting whose allowed to give and therefore the donors pool is

actually contracting. Meanwhile, as baby boomers approach the age of 55+, they're out to get replacement parts: new elbows, new knees, new hips, all of which are highly blood intensive surgeries. As a result, in the last 5 years, the rate of growth in the blood supply has dropped only 3%. But the demand has grown to +5%. Those numbers are projected to go further in each direction over the next few years and in fact, short term blood shortages are now becoming routine across the country.

Alright. What about the other aspect of this tolerability to get into the bloodless surgery market? I'll go through this very briefly, but quite simply, there are two broad scale techniques that are used to avoid blood from a stranger today. Predonation of your own blood, or the use of Erythropoeitin to increase your blood count before surgery. Both are supplemented in most cases by the use of cell salvage, where a certain portion of your bleed out in a surgery can be recaptured and recirculated to your body. From a pharma-economical perspective, this process is incredibly wasteful. Half of pre-donated blood and half of the Erythropoeitin use is in fact not needed, because half of the people end up not needing a transfusion and so all that gets thrown away. Beyond that, half of the people who do need a transfusion use three units instead of the two that is generally pre-donated, and as a result they actually end up getting blood from a stranger anyway. So, 75% of blood avoidance techniques are "a failure" either because they are unnecessary or because they do not succeed in the primary objective, to avoid getting blood from a stranger. From a cost standpoint, this puts us in a very strong position. If you looked at it from the position of two patients going through each of these procedures, someone who pre-donates blood, generates their blood at a cost of $350 a unit. For two patients, that's a total of 4 units. Two of which get transfused, for a total cost of $1,600. From an insurer's standpoint or a hospital's standpoint, that means this program costs $800 a patient. Erythropoeitin costs twice as much, $1,600 a patient. Hemopure, because you don't use it unless you need it, only one of the two patients will actually require the product and there is the reward of the savings from the perspective of both the hospital and the payer because on that basis the cost per patient is only $800. Of course, cost isn't this whole picture. On the left hand side, pre-donation, you're dealing with two visits to the dr.'s office, the discomfort of two extractions for the blood as well as the cost internal to the hospital in handling that blood. So in both cases, we think we represent an attractive pharma-economical alternative within this market.

Many of you have seen a summary of clinical experience which is about the same as before, so I'm going to run through it quickly here. We have an impressive overall clinical track record. Over 200 pre-clinical studies, 22 human clinical trials, over 800 patients exposed to the product in a clinical setting, a lot of compassionate use experience, a lot of veterinary experience in the open-

market and some good patent protection behind that. Our studies on all kinds of surgeries and represents a broad experience for the product and again with over 800 patients using the product in a clinical setting. From the standpoint of efficacy, the agreed upon standard with the FDA for the efficacy of the product was the 35% of patients in our trials, on a trial where they could switch the red blood cells at any time, that within the seven day period of the trial, excuse me, six day period of trial, that less than 35% or more would be able to stay on Hemopure throughout the course of the trial. In our two phase III trials, in general surgery and orthopedic surgery, we easily surpassed that standard with 43% and 59% respectively. When you look at the internals, it's even more impressive. Within the first day, 96% of Hemopure patients stayed on Hemopure, after seven days 70% were on Hemopure. Unfortunately under the protocol of the trial no patients were allowed to get any Hemopure after day six, so by the time the full monitoring period was over, only 59% were still on hemopure only, but again that easily surpassed 35% standard set by FDA.

From a safety standpoint, in our pivotal trial, we agreed before the trial began with the FDA to use as our primary safety endpoint something called a [Seep?] study. Which is basically a blinded analysis of all the case report forms by a panel of doctors who would examine each patient, create their own score of adverse events and then rank the product use again on a blinded basis in terms of how safe it was for the patient. After all the patients were rated by at least two blinded doctors, we broke the blind, and compared the accumulative scores between our products and red blood cells and achieved a safety objective which was to confirm that our product was not inferior to red blood cells with respect to overall medical risks.

As I say, we have a strong group of intellectual property. 24 U.S. patents and over 60 international patents. The majority extend to 2014 or later. For those of you with exceptionally high corrective power on your glasses, you'll see that basically, there are only six patents between now and 2014 that expire. The majority of that intellectual property is recovered in later patents and we are issuing new patents all the time. From a manufacturing standpoint, we currently have a capacity of 75,000 units at our Cambridge, Massachusetts facility. We're in the process of expanding that to roughly 100,000 units, and we expect that process to be complete by the middle of next year. We are still in active negotiation for the financing necessary to construct a 500,000 unit facility in Sumter South Carolina. Which could be up and operating basically roughly three years after the shovel first hits the ground, and frankly, based on the units produced and the significantly superior cost structure units produced there, really is going to be the pivotal point to getting this company to full profitability. From a competitive standpoint, we are the only company using bovine hemoglobin that confers unusual stability and characteristics for our product compared to our

competition. As probably many of you know, Northfield, our principal competitor at this time, is beginning Phase III trials of their product for use in trauma, hemosol, is currently on chemical hold due to safety issues. It is unclear when or if they will progress from that point.

Our strategy from here is pretty straightforward. We're going to make ready for U.S. launch in orthopedic surgery. Our strategy uses a team of experienced orthopedic device salespeople to persuade orthopedic surgeons this is the important next step in high technology to incorporate in their practice. When they insist that it be distributed in the hospitals, we will follow up with medical science liaisons who will facilitate the training for anesthetists, anesthesiologists, floor nurses and intensivists in order to ensure that the product is safely and effectively used within the hospital scene. Secondarily, we are going to work to grow our revenues within our veterinary business within our South African business and through additional alliances. Our licensing agreements principally focused on geographic usage and geographies we don't intend to penetrate on our own. I've outlined for you the clinical program which will be focused on trauma and cardiac ischemia over the next year or two. Our aim is to get going on a cancer program sometime late in 2004. From a balance sheet standpoint, we have continually strengthened our balance sheet during this year. In fact, this graphic probably gives you the best picture. Cash on hand is now in the ball park of $30,000,000 and we've been demonstrating repeatedly our ability to raise the money necessary to keep this company on a strong cash footing.

That's our overview of our picture. I appreciate very much your interest in this presentation this afternoon. I think we're going to do a break out in the State Suite. I look forward to hopefully talking to several of you there.